

WE CLAIM:

1. A pharmaceutical formulation comprising an exendin or an exendin agonist peptide, a buffer, and an iso-osmolality modifier, said pharmaceutical formulation having
5 a pH of between about 3.0 and about 7.0.

2. A pharmaceutical formulation according to claim 1 wherein said buffer is an acetate buffer.

3. A pharmaceutical formulation according to claim 1 wherein said iso-osmolality modifier is mannitol.

10 4. A pharmaceutical formulation according to claim 1 wherein said pH is between about 4.0 and about 6.0.

5. A pharmaceutical formulation according to claim 1 wherein said pH is between about 4.0 and about 5.0.

15 6. A pharmaceutical formulation according to claim 1, further comprising a preservative.

7. A pharmaceutical formulation according to claim 5 wherein said preservative is m-cresol.

8. A pharmaceutical formulation comprising an exendin or an exendin agonist peptide, an acetate buffer, and
20 mannitol, said pharmaceutical formulation having a pH of between about 3.0 and about 7.0.

9. A pharmaceutical formulation according to claim 7, further comprising m-cresol.

25 10. A pharmaceutical formulation according to claim 8, wherein said pH is between about 4.0 and about 6.0.

11. A pharmaceutical formulation according to claim 8, wherein said pH is between about 4.0 and about 5.0.

12. A pharmaceutical formulation according to any of
30 claims 1-11, wherein said pharmaceutical formulation is a liquid.

13. A pharmaceutical formulation according to any of claims 1-11, wherein said pharmaceutical formulation is lyophilized.

14. A parenteral liquid pharmaceutical formulation,
5 comprising about 0.005% to about 0.4% (w/v) of an exendin or an exendin agonist peptide in an aqueous system, about 0.02% to 0.5% (w/v) of an acetate, phosphate, citrate, or glutamate buffer, about 1.0% to about 10% (w/v) of a carbohydrate or polyhydric alcohol iso-osmolality modifier
10 (preferably mannitol) said formulation having a pH of between about 3.0 and about 7.0.

15. The parenteral liquid pharmaceutical formulation according to claim 14 wherein said formulation comprises from about 0.005 to about 0.05% (w/v) of an exendin or an
15 exendin agonist peptide.

16. The parenteral liquid pharmaceutical formulation according to claim 14 wherein said formulation comprises from about 0.005 to about 0.02% (w/v) of an exendin or an
exendin agonist peptide.

20 17. The parenteral liquid pharmaceutical formulation according to claim 14 wherein said polyhydric alcohol is selected from the group consisting of sorbitol, mannitol, inositol, glycerol, xylitol, and polyethylene glycols.

25 18. The parenteral liquid pharmaceutical formulation according to claim 17 wherein said polyhydric alcohol is mannitol.

19. The parenteral liquid pharmaceutical formulation according to claim 14 wherein said carbohydrate is selected from the group consisting of galactose, arabinose, and
30 lactose.

20. The parenteral liquid pharmaceutical formulation according to claim 14 which is an isotonic or iso-osmolar solution in an aqueous continuous phase.

21. The parenteral liquid pharmaceutical formulation
5 according to claim 14 wherein said pH is between about 4.0 and about 6.0.

22. A parenteral liquid pharmaceutical formulation according to claim 14 wherein said pH is between about 4.0 to 5.0.

10 23. The parenteral liquid pharmaceutical formulation according to claim 14, further comprising from about 0.005% to 1.0% (w/v) of an anti-microbial preservative.

24. The parenteral liquid pharmaceutical formulation according to claim 23 wherein said anti-microbial
15 preservative is selected from the group consisting of m-cresol, benzyl alcohol, methyl, ethyl, propyl parabens, butyl parabens, and phenol.

25. The parenteral liquid pharmaceutical formulation according to claim 24 wherein said anti-microbial
20 preservative is m-cresol.

26. The parenteral liquid pharmaceutical formulation according to claim 14 wherein said carbohydrate or polyhydric alcohol is replaced by up to about 0.9% saline.

27. The parenteral liquid pharmaceutical formulation
25 according to claim 26 which is an isotonic or iso-osmolar solution in an aqueous continuous phase.

28. The formulation according to any of claims 1-11, 14-26 or 27, wherein said formulation is a liquid.

29. The formulation according to any of claims 1-11, 14-26 or 27, wherein said formulation is a lyophilized unit-dose or multi-dose formulation containing a bulking agent.

30. The formulation according to claim 28 wherein said
5 bulking agent is an iso-osmolality modifier.

31. The formulation according to claim 28, further comprising a surfactant.

32. The formulation according to claim 29 wherein
10 said surfactant comprises about 0.1% to about 1.0% (w/v) of a non-ionic detergent.

33. The formulation according to claim 30 wherein said surfactant is polysorbate 80.

34. A solid or dry powder pharmaceutical formulation
15 comprising from between about 1% to about 100% (w/w) of an exendin or an exendin agonist peptide and, wherein said exendin or exendin agonist peptide is present in an amount that is less than about 100% (w/w), a bulking agent.

35. The pharmaceutical formulation according to claim
20 34 wherein said bulking agent comprises from about 0% to about 99% (w/w) of a carbohydrate or polyhydric alcohol.

36. The pharmaceutical formulation according to claim 34, further comprising a salt.

37. The pharmaceutical formulation according to claim 34 which includes a bulking agent and a salt.

25 38. The pharmaceutical formulation according to claim 34, further comprising a surfactant.

39. The pharmaceutical formulation according to claim 37 wherein said surfactant comprises about 0.1% to about 1.0% (w/w) of a non-ionic detergent.

40. The pharmaceutical formulation according to claim 38 wherein said surfactant is polysorbate 80.

41. A pharmaceutical formulation comprising up to about 50 mg/ml of an exendin or an exendin agonist in 30mM acetate buffer, and mannitol, said formulation having a pH of about 4.5.

42. The pharmaceutical formulation according to claim 41, further comprising a preservative.

43. A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising injecting said subject with about 0.1 to about 0.5 µg per kilogram of an exendin or an exendin agonist.

44. The method according to claim 43 wherein said injection is administered to said subject from one to three times per day.

45. The method according to claim 44 wherein said injection is administered to said subject two times per day.

46. A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising orally administering to said subject about 500 to about 12,000 µg per day of said exendin or exendin agonist in single or divided doses.

47. The method according to claim 46 wherein from about 500 to about 5,000 µg per day of said exendin or exendin agonist is orally administered.

48. A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising administering about 100 to about 12,000 µg per day of said exendin or exendin agonist to the pulmonary system of said subject in single or divided doses.

49. The method according to claim 48 wherein from about 500 to about 1,000 µg per day of said exendin or exendin agonist is administered to the pulmonary system of said subject in single or divided doses.

5 50. A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising nasally administering from about 10-1000 to about 1200-12,000 µg per day of said exendin or exendin agonist to said subject in single or divided doses.

10 51. The method according to claim 50 wherein from about 10 to about 1,200 µg per day of said exendin or exendin agonist is nasally administered.

52. A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising the
15 buccal administration of from about 10-1000 to about 1200-12,000 µg per day of said exendin or exendin agonist to said subject in single or divided doses.

53. The method according to claim 52 wherein from about 10 to about 1,200 µg per day of said exendin or
20 exendin agonist is administered.

54. A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising the sublingual administration of from about 10-1000 to about 1200-8,000 µg per day of said exendin or exendin agonist to
25 said subject in single or divided doses.

55. The method according to claim 54 wherein from about 10 to about 1,200 µg per day of said exendin or exendin agonist is administered.

56. A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising injecting said subject with about 1 μ g-30 μ g to about 1 mg of an exendin or exendin agonist per day.

5 57. The method according to claim 56 wherein said injection is a peripheral injection.

58. The method according to claim 56 wherein said subject is injected with about 1-30 μ g to about 500 μ g of said exendin or exendin agonist per day.

10 59. The method according to claim 56 wherein said subject is injected with about 1-30 μ g to about 50 μ g of said exendin or exendin agonist per day.

60. The method according to claim 56 wherein said subject is injected with about 3 μ g to about 50 μ g of said
15 exendin or exendin agonist per day.

61. A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising injecting an exendin or an exendin agonist into said subject in an amount equal to from about 0.005 μ g/kg per dose to
20 about 0.2 μ g/kg per dose.

62. The method according to claim 61 wherein said dose is from about 0.02 μ g/kg per dose to about 0.1 μ g/kg per dose.

63. The method according to claim 61 wherein said dose is from about 0.05 μ g/kg per dose to about 0.1 μ g/kg per dose.

25 64. The method according to any of claims 61, 62 or 63, wherein said doses are administered to said subject from 1 to 4 times per day.

65. The method according to any of claims 61, 62 or 63, wherein said doses are administered to said subject from 1 to
30 2 times per day.

66. A method for increasing the sensitivity of a a subject to exogenous or endogenous insulin, comprising administering an effective amount of exendin or an exendin agonist to said subject.

5 67. The method according to claim 66 wherein said exendin or an exendin agonist is administered by nasal administration.

10 68. The method according to claim 66 wherein said exendin or an exendin agonist is administered by oral administration.

69. The method according to claim 66 wherein said exendin or an exendin agonist is administered by pulmonary administration.

15 70. The method according to claim 66 wherein said exendin or an exendin agonist is administered by buccal administration.

71. The method according to claim 66 wherein said exendin or an exendin agonist is administered by sublingual administration.

20 72. The method according to claim 66 wherein said exendin or an exendin agonist is administered by intra-tracheal administration.

73. The method according to claim 66 wherein said exendin or an exendin agonist is administered by injection.

25 74. The method according to claim 73 wherein said injection is a subcutaneous injection.

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